IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., Inc. Plaintiff, v. RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Defendant.	)	C.A. No. 07-229 (GMS)
RANBAXY INC. and RANBAXY LABORATORIES LIMITED, Counterclaim Plaintiff, v. MERCK & CO., Inc. Counterclaim Defendant.	)	

DEFENDANTS RANBAXY INC.'S AND RANBAXY LABORATORIES LIMITED'S ANSWERING BRIEF IN OPPOSITION TO MERCK'S MOTION TO FILE ITS FIRST SUPPLEMENTAL COMPLAINT

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Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited (collectively "Ranbaxy") oppose Merck's motion for leave to file its proposed first supplemental complaint.

I. INTRODUCTION

Ranbaxy opposes Merck's attempt to supplement its complaint, because Merck's motion is nothing more than a transparent attempt to evade the consequences of its deliberate decision to file its complaint before seeking correction of its admittedly defective patent. Because Merck elected to file suit prior to seeking correction of the patent in suit, and the certificate of correction issued after Merck's cause of action arose, the certificate is a nullity which can have no effect in the present litigation. Merck now attempts an end-run around the mandate of the Federal Circuit in *Southwest Software Inc. v. Harlequin Inc.*, 226 F.3d 1280 (Fed. Cir. 2000) and this Court's decision in *ISCO Int'l v. Conductus, Inc.*, 2002 U.S. Dist LEXIS 21706 (D. Del. Nov. 8, 2002). Merck's motion should be denied on the ground that it is futile, because the proposed supplemental complaint could not in any event change the fact that the present action must proceed on the basis of the original patent, without reference to the certificate of correction.

II. NATURE AND STAGE OF PROCEEDINGS

This is an action for patent infringement under 35 U.S.C. §271(a), (b) and (c) and under 35 U.S.C. §271(e)(2) based on Ranbaxy's future importation and sale of a pharmaceutical product containing imipenem and cilastatin, which Merck alleged in its original complaint infringes U.S. Patent 5,147,868 ("'868 patent"). Merck filed its original complaint on April 30, 2007, and Ranbaxy filed its Answer and Counterclaims, seeking a declaratory judgment of invalidity and noninfringement of the '868 patent as issued, on June 21, 2007.

Fact discovery is scheduled to end on May 30, 2008, and opening and rebuttal expert reports are due on March 28, 2008 and April 25, 2008. The Court has scheduled a one-week trial commencing on September 15, 2008.

The parties have completed claim construction briefing, and a *Markman* hearing is scheduled for February 7, 2008.

The date for amending the pleadings was originally January 4, 2008, but the Court extended the date to January 11, 2008 on request of the parties. Merck subsequently moved for leave to file a Supplemental Complaint. Ranbaxy opposes the filing of the Supplemental Complaint because each of the new counts relates to a Certificate of Correction issued on November 6, 2007, after Merck's complaint and Ranbaxy's counterclaims were filed, and which is not effective in this case.

III. COUNTERSTATEMENT OF FACTS

A. Ranbaxy's ANDAs in This Litigation

1. On December 26, 2006, Ranbaxy filed an Abbreviated New Drug Application ("ANDA") directed to imipenem/cilastatin sodium seeking approval to engage in the commercial manufacture, use, offer for sale and sale of injectable products comprising imipenem and cilastatin sodium.

2. By letter of January 22, 2007, Ranbaxy notified Merck of its ANDA filing, stating that its proposed injectable products would not infringe any valid claim of Merck's '868 patent. (Farnan Decl. Ex. 1)[1]. Ranbaxy also informed Merck that Ranbaxy planned to begin marketing its proposed injectable products immediately upon approval. Ranbaxy requested from Merck a Covenant Not to Sue (Farnan Decl. Ex. 1), which Merck denied.

3. Merck filed the instant suit on April 30, 2007. Merck's Complaint contained two distinct Counts alleging patent infringement against Ranbaxy, each seeking relief separately from the other, based on the particular bases of infringement set forth in each Count. (Complaint for

[1] Exhibits are described in and attached to the January 31, 2008 Declaration of Kelly E. Farnan, Esq. being contemporaneously filed herewith.

Patent Infringement ("Complaint"), D.I. 1).

4. Merck's Count I alleged infringement based on Ranbaxy's having "made meaningful preparations for, and engag[ing] in activities directed toward, infringing the '868 patent," (Complaint, D.I. 1, ¶14), as well as "a refusal to change the course of their actions in the face of acts by Merck." (Complaint, D.I. 1, ¶15). As a result, Merck alleged infringement under 35 U.S.C. §271 (a), (b) or (c), based on the "manufacture, use, sale or offer for sale of the ANDA products in the United States or importation of the ANDA products into the United States." (Complaint, D.I. 1, ¶16). Merck sought as relief for the acts described in Count I, *inter alia*, an injunction under 35 U.S.C. §283 prohibiting Ranbaxy from manufacturing, using, selling and offering for sale its injectable products comprising imipenem and cilastatin sodium. (Complaint, D.I. 1, ¶20).

5. Separately, Merck's Count II alleged infringement of the '868 patent under 35 U.S.C. §271(e)(2) based on Ranbaxy having filed an ANDA, seeking approval to commercialize a drug formulation claimed in the '868 patent prior to patent expiration. (Complaint, D.I. 1, ¶¶26-28). Merck sought as relief for the acts described in Count II, *inter alia*, an order under 35 U.S.C. §271(e)(4) that the effective date of the approval of Ranbaxy's ANDA be a date that is not earlier than the expiration date of the '868 patent, or any later expiration of exclusivity to which Merck may be entitled as well as an injunction prohibiting the commercial manufacture, use, sale, and offer for sale of Ranbaxy's injectable products comprising imipenem and cilastatin sodium. (Complaint, D.I. 1, Prayer For Relief, subsection c).

6. On June 21, 2007, Ranbaxy filed its Answer and Counterclaims in response to Merck's Complaint (Answer and Counterclaims of Defendants Ranbaxy Inc. and Ranbaxy Laboratories Limited (Answer), D.I. 10). Ranbaxy's Counterclaim I is directed to non-infringement of the '868 patent by Ranbaxy's proposed injectable products, defined as injectable products comprising imipenem and cilastatin sodium. (Answer, D.I. 10, ¶10).

Specifically, Ranbaxy stated:

> 55. Ranbaxy has not manufactured, used, sold, or offered for sale in the United States, or imported into the United States, any products that infringe any valid claim of the '868 patent, either literally or under the doctrine of equivalents.
>
> 56. Ranbaxy's proposed injectable products do not infringe and does not and has not induced infringement or contributed to infringement of any valid claim of the '868 patent, either literally or under the doctrine of equivalents.

(Answer, D.I. 10, ¶¶55-56). Ranbaxy's Counterclaims of non-infringement are not limited to specific products recited in any particular ANDA. Rather, Ranbaxy's non-infringement Counterclaims apply to all of its proposed injectable products.

7. Similarly, Ranbaxy's Counterclaim II is directed to the invalidity of the '868 patent for the statutory and other bases alleged:

> 59. Each and every claim of the '868 patent is invalid for failure to meet the statutory requirements of Title 35 of the United States Code, including, but not limited to, the failure to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112.
>
> 60. Each and every claim of the '868 patent is invalid for failing to meet judicially-created requirements for patentability and enforceability of patents, including but not limited to, obviousness-type double patenting based on U.S. Patent No. 4,539,208.

(Answer, D.I. 10, ¶¶59-60). Counterclaim II does not seek invalidity in connection with any particular Ranbaxy ANDA or proposed injectable product.

8. Finally, Ranbaxy's Counterclaim III is directed to the unenforceability of the '868 patent based on prosecution laches. (Answer, D.I. 10, ¶62). Nothing in this Counterclaim is in any way limited to any particular Ranbaxy ANDA or proposed injectable product.

9. In August, 2007, Ranbaxy filed two additional ANDAs directed to different

packaging of its imipenem/cilastatin proposed drug product. Ranbaxy notified Merck of the filings by letter of September 14, 2007. (Farnan Decl. Ex. 2).

10. On September 21, 2007, Merck propounded both Interrogatories and Document Requests on Ranbaxy, directed to Ranbaxy's imipenem/cilastatin proposed drug products included in ***all*** of its ANDAs relating to imipenem/cilastatin products. Specifically, Merck's Interrogatories defined "Ranbaxy's ANDA" as "any and every ANDA that Ranbaxy has filed covering its products comprising imipenem and cilastatin," and "Ranbaxy's ANDA products" as any and every pharmaceutical composition product that is the subject of any ANDA that Ranbaxy has filed covering products comprising imipenem and cilastatin." (Farnan Decl. Ex. 3 at p. 2; Ex. 4 at p. 2).

11. In early October, 2007, counsel for the parties discussed Initial Disclosures and specifically the production of all three ANDAs as part of those disclosures. Ranbaxy stated in its Initial Disclosures under Rule 26(a)(1):

> Undersigned counsel for RANBAXY is today producing the non-privileged and non-work product documents collected to date concerning its defenses, ***including copies of three separate ANDAs seeking approval to engage in the commercial manufacture, use and sale of three different formulations of injectable products comprising imipenem and cilastatin***.

(Farnan Decl. Ex. 5 at p. 6).

12. On October 17, 2007, Ranbaxy produced over 16,300 pages of documents to Merck, including all three ANDAs relating to imipenem and cilastatin. (Farnan Decl. Ex. 6).

13. On October 22, 2007, Ranbaxy responded to Merck's written discovery requests, which encompassed all three of Ranbaxy's ANDAs relating to imipenem/cilastatin products. (Farnan Decl. Ex. 3 at p. 2). Ranbaxy did not object to Merck's definitions of "Ranbaxy's ANDA" and "Ranbaxy's ANDA products" as encompassing all three ANDAs and products described therein. (Farnan Decl. Ex. 7 at pp. 7-8). Rather, Ranbaxy responded to

Merck's requests with respect to all three ANDAs and related products. (*See, e.g.*, Farnan Decl. Ex. 7 at p. 10 (stating "[t]he products described in Ranbaxy's ANDAs produced to Merck on October 17, 2007 are referred to herein as "Ranbaxy's product" for convenience.")). Repeatedly throughout Ranbaxy's Response to *e.g.*, Interrogatory 1, Ranbaxy provided its non-infringement position with respect to its proposed products described in all three of its ANDAs. (Farnan Decl. Ex. 7 at pp. 10-13). In response to Interrogatory 14, Ranbaxy stated that "initial preparations for manufacturing Ranbaxy's ANDA products to be imported into the United States has begun." (Farnan Decl. Ex. 7 at p. 32). Thus, Ranbaxy's discovery responses incorporated Merck's broad definition of "Ranbaxy's ANDA products" and included all three ANDAs.

14. From the time that Ranbaxy filed its additional ANDAs in August, both Merck and Ranbaxy have treated them as part of the case and as having been framed by the original pleadings of the parties. Merck has propounded broad discovery based on all three ANDAs and has received responsive information from Ranbaxy accordingly. In its Motion, Merck agrees, stating that "[d]iscovery has been proceeding on all three ANDAs and Products I, II, and III." (Merck's Brief In Support Of Its Motion For Leave to File Its First Supplemental Complaint ("Merck's Brief"), D.I. 49 at p. 2.; *see also* Farnan Decl. Ex. 8; Ex. 9; Ex. 10; Ex. 11 at p. 3; Ex. 12 at p. 2). At no time has Merck ever limited the scope of its discovery requests to the originally-filed ANDA, refused to accept discovery on the two additional ANDAs, or otherwise informed Ranbaxy that it did not consider the two additional ANDAs to be within the scope of the case as originally filed.

B. The Secret Certificate of Correction Proceeding

15. In its January 22, 2007 Notice letter, Ranbaxy specifically advised Merck that there was a substantive omission in the chain of priority listed in the '868 patent, and that as a result, the '868 patent was only entitled to an effective filing date of February 10, 1983,

the date of filing the '577 application (in the chain that led to the issuance of the '868 patent). (Farnan Decl. Ex. 1 at p. 3). Ranbaxy also pointed out that several publications of the claimed subject matter occurred more than one year prior to the filing of the '577 application. (Farnan Decl. Ex. 1 at p. 3).

16. Although Merck's April 30, 2007 Complaint alleged that Ranbaxy's notice letter was "devoid of an objective good faith basis in either fact or the law" (Complaint, D.I. 1, ¶31), Merck filed a petition at the U.S. Patent Office on May 17, 2007, two weeks ***after*** the filing of this suit, seeking *on an expedited basis,* correction of the '868 patent's defective priority claim. Merck attached a copy of the Complaint to its petition as a basis for requesting expedited consideration. (Farnan Decl. Ex. 13)[2]. Merck never informed Ranbaxy or the Court of this filing.

17. On September 19, 2007, the Court held a Scheduling Conference under Rule 16. Counsel for Ranbaxy stated that the effective filing date of the claims was an issue in this case, because it would determine what was relevant prior art and what was not. (Farnan Decl. Ex. 14 at pp. 5-6). Merck's counsel responded at that Conference that the issue of effective filing date was "always" in the case or at least "usually" in the case, (Farnan Decl. Ex. 14 at 8), but at no point informed Ranbaxy or the Court about the *ex parte* actions it was taking at the Patent Office to alter the filing date of the patent-in suit.

18. On October 17, 2007, Merck served its Initial Disclosures along with a first production of documents. However, Merck did not "disclose" with its October 17, 2007 Initial Disclosures any documents relating to the PTO proceeding or any person with knowledge of the proceeding as affecting a claim or defense in this case. (Farnan Decl. Ex. 15). Further, on October 17, 2007, Merck produced "some file histories" but elected not to produce a current

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[2] Exhibit 13 contains bates labeled Request for Expedited Certificate of Correction documents produced by Merck on October 26, 2007, following repeated requests by Ranbaxy.

file history of the '868 patent which would necessarily contain papers related to the PTO proceeding that had commenced in May 2007. (*See* Farnan Decl. Ex. 11 at 2).

19. Shortly thereafter, as a result of checking the PTO website for any possible updates to the '868 patent file history, Ranbaxy first learned of Merck's plan to secretly attempt to "correct" the '868 patent-in-suit. Inspection of the PTO website on October 19, 2007 revealed the following cryptic notation dated October 3, 2007— "Post Issue Communication – Certificate of Correction." (Farnan Decl. Ex. 16).[3] Ranbaxy immediately contacted Merck requesting further information as to the nature and substance of the proposed alterations to the patent along with copies of whatever papers had been filed (Farnan Decl. Ex. 17) but received no response until October 24 (Farnan Decl. Ex. 18; Ex. 8). Merck refused to produce the documents. (Farnan Decl. Ex. 8).

20. As one alleged justification for refusing to produce the Certificate of Correction papers, counsel for Merck even took the untenable position that the proceeding at the Patent Office was confidential and not open to the public. (Farnan Decl. Ex. 9). A series of letters and phone calls followed, in which Ranbaxy reiterated that actions seeking alteration of the '868 patent could have a direct bearing on the validity and enforceability issues in the case and that Ranbaxy *and* the general public are entitled to access to the same. (*See, e.g.*, Farnan Decl. Ex. 18 and Ex. 9).

21. Only when Ranbaxy again advised Merck that it would seek the assistance of the Court if the documents were not immediately produced did Merck produce the withheld file on October 26, 2007. (Farnan Decl. Ex. 9; Ex. 10). This was the first day Ranbaxy learned that Merck had been secretly engaged in a PTO proceeding to alter the patent-in-suit since May 2007.

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[3] That notation remains the only information on the PTO PAIR website concerning the Certificate of Correction proceeding.

22. During the time that Merck refused to produce the Certificate of Correction file, Ranbaxy's counsel independently tried to obtain it from the PTO, but were told that file was inaccessible because it had been sent off-site to have the Certificate printed. On November 6, 2007, the PTO issued a Certificate of Correction of the '868 patent, which is the basis of Merck's motion at hand. (Farnan Decl. Ex. 19).

IV. ARGUMENT

Merck admits that the '868 patent-in-suit issued without any claim to benefit under 35 U.S.C. §120 of an application which it characterizes as a "parent" application. (Merck's Brief, D.I. 49 at p. 3). The certificate of correction added to the specification a reference to U.S. Patent Application Ser. No. 06/188,178, which was filed on September 17, 1980, and was abandoned on February 10, 1983. (Farnan Decl. Ex. 20). Because Merck neglected to claim benefit of the '178 application, and failed to seek correction of this error prior to filing the present action, the earliest filing date to which any claim of the '868 patent can be entitled in the present litigation is the filing date of U.S. Patent Application Ser. No. 06/465,577 ("'577 application"), which is February 10, 1983.

Merck states that this admitted deficiency in the '868 patent is "a minor error on the face of the '868 patent and in the first paragraph of the specification." (Merck's Brief, D.I. 49 at p. 3). In fact, the consequence of Merck's actions is that each of the asserted claims is anticipated or clearly obvious in view of Merck's public disclosure of compounds within the scope of the '868 patent, including cilastatin, more than one year prior to the effective filing date of the '868 patent on February 10, 1983. As confirmed by the prosecution history of the '868 patent, at latest by September 22, 1980, Merck admittedly described the alleged invention of the '868 patent, including cilastatin, in a published Abstract which is prior art under 35 U.S.C. §102(b). (Farnan Decl. Ex. 20). At latest by September 24, 1980, in conjunction with the Abstract Merck

admittedly made a poster presentation at a trade show in New Orleans, which included charts disclosing numerous additional compounds within the scope of the asserted claims. (Farnan Decl. Ex. 20). Beyond any reasonable doubt, the invention claimed in the '868 patent was described in a printed publication in the United States under 35 U.S.C. §102(b) more than one year before the effective filing date of the '868 patent as issued.

Merck's failure to claim benefit of the '178 application is thus not a minor or technical deficiency, but instead is a critical error which results in the invalidity of every asserted claim of the '868 patent. Because the law is unmistakably clear that Merck's belated certificate of correction can have no effect in the present litigation, this issue is effectively dispositive of the validity of all asserted claims of the unaltered '868 patent. If the Court agrees with Ranbaxy that the certificate of correction is inapplicable in the present action, the asserted claims are anticipated by or obvious over at least Merck's September 22-24 Abstract and poster presentation. (Farnan Decl. Ex. 20).

A. The Certificate of Correction

In the present case, Merck surreptitiously filed a petition for a certificate of correction on May 17, 2007, after filing its complaint in the present action on April 30, 2007, while concealing this action both from Ranbaxy and from the Court, and secretly obtained a certificate of correction which issued on November 6, 2007. (Counterstatement of Facts ("C.O.F."), ¶16). Merck improperly concealed its actions from Ranbaxy and the Court, by failing to disclose the petition or any other document relating to the certificate of correction in its initial disclosures under Fed. R. Civ. P. 26, which included only a partial file history of the '868 patent without these critical documents that had been filed months earlier. (C.O.F. ¶18). After Ranbaxy independently determined that Merck had filed undisclosed papers in the PTO relating to a certificate of correction, Merck continued to refuse to disclose this information to Ranbaxy (C.O.F. ¶19), despite Ranbaxy's demands (C.O.F. ¶¶ 20-21) and its clear rights as a defendant in

the present action. (C.O.F ¶¶15-22). By this subterfuge, Merck obtained the certificate of correction while denying Ranbaxy any opportunity to intervene in the USPTO, or to seek appropriate action by this Court.

The timing of the petition for the certificate of correction is striking. In a letter dated January 22, 2007, Ranbaxy informed Merck of a pending ANDA relating to its proposed generic product, and of Ranbaxy's intention to commence sale of the generic product as soon as its ANDA is approved. (C.O.F. ¶15). In this letter, Ranbaxy further informed Merck of Merck's failure to claim benefit of the '178 application, and that several publications of the claimed subject matter occurred more than one year prior to the effective filing of the '868 patent. (C.O.F. ¶15). Ranbaxy thus directly and unequivocally informed Merck of Ranbaxy's reliance on this deficiency appearing on the face of the '868 patent.

With full knowledge of the alleged error in the '868 patent, and notice of Ranbaxy's reliance on the patent's disclosed effective filing date, Merck elected to file the present action on April 30, 2007, yet postponed filing its petition for a certificate of correction until May 17, 2007. The reason for this action is clear from the record. Merck sought "expedited consideration" of its petition in the PTO based on the present litigation, and filed a copy of the complaint with its petition. (C.O.F. ¶16). If Merck had waited to file the present action until a certificate of correction issued (without such "expedited consideration"), the lawsuit might well have been delayed until after Ranbaxy's launch of the generic product. Furthermore, Merck would have to risk additional competition from other generic manufacturers, without being able to enforce its uncorrected patent in other litigation commenced prior to issuance of the certificate of correction. Faced with this dilemma, Merck's experienced attorneys made the conscious decision to file the action first and correct the patent later. Merck must now accept the consequences of its deliberate decision.

B. The Certificate of Correction Can Have No Effect in the Present Litigation

The law is unmistakably clear that a certificate of correction which issues after the patentee's cause of action arises is ineffective for any purpose in an action filed prior to issuance of the certificate of correction. *See Southwest Software Inc. v. Harlequin Inc.*, 226 F.3d 1280 (Fed. Cir. 2000); *ISCO Int'l v. Conductus, Inc.*, 2002 U.S. Dist LEXIS 21706 (D. Del. Nov. 8, 2002) ("*ISCO I*"); *ISCO Int'l v. Conductus, Inc.*, 2003 U.S. Dist LEXIS 3262 (D. Del. Mar. 6, 2003) ("*ISCO II*"). This result is compelled by the language of 35 U.S.C. §255 which permits certificates of correction to correct a clerical or typographical or minor mistake[4] of an applicant:

> Whenever a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office, appears in a patent and a showing has been made that such mistake occurred in good faith, the Director may, upon payment of the required fee, issue a certificate of correction, if the correction does not involve such changes in the patent as would constitute new matter or would require re-examination. Such patent, together with the certificate, shall have the same effect and operation in law *on the trial of actions for causes thereafter arising* as if the same had been originally issued in such corrected form. (emphasis added).

According to the plain language of the statute, a certificate of correction which issues after a cause of action arises has no effect, and the trial of an infringement action filed prior to issuance of a certificate of correction must proceed on the basis of the uncorrected, originally issued patent. *Southwest Software Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1297 (Fed. Cir. 2000).

In *Southwest Software*, the Federal Circuit held that "a certificate of correction that was issued under 35 U.S.C. §254 to add certain material to the . . . patent is not effective for purposes of this action" and remanded the case to the district court to determine the validity of the patent

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[4] Ranbaxy by no means suggests or concedes that the certificate of correction surreptitiously obtained by Merck was lawfully issued, or is valid. If the certificate of correction has any effect in the present litigation, Ranbaxy reserves its right to contest the validity and effect of the certificate of correction.

"absent the added material." 226 F.3d at 1283. In *Southwest Software*, the error in the patent was a printing mistake of the PTO, which failed to include an appendix containing source code in the printed patent. *Id.* at 1294. After filing the lawsuit, the plaintiff discovered that the appendix was missing from a certified copy of the patent, and requested a certificate of correction which was granted by the PTO. *Id.* at 1287. The holding of the Federal Circuit as to the effect of the certificate of correction in the lawsuit is unequivocal:

> Southwest's cause of action against Harlequin and ECRM arose before the certificate of correction was issued. We hold that the certificate of correction that added the Program Printout Appendix is *not to be given effect in this pre-certificate lawsuit*. The certificate of correction is only effective for causes of action arising after it was issued. This interpretation of § 254 is based upon the language of the statute. (emphasis added)

Id. at 1294. As the court further explained, the statute

> also provides that "every such patent, together with such certificate, shall have the same effect and operation in law on the trial of actions *for causes thereafter arising* as if the same had been originally issued in such corrected form." *Id.* (emphasis added). We conclude that this language requires that, for causes arising after the PTO issues a certificate of correction, the certificate of correction is to be treated as part of the original patent—i.e., as if the certificate had been issued along with the original patent. By necessary implication, for causes arising before its issuance, the certificate of correction is not effective.

Id. at 1295.

Accordingly, the court held that the certificate of correction issued after the lawsuit was filed in *Southwest Software* was "not effective for purposes of this action" and that the omitted appendix "cannot be considered part of the ... patent for purposes of this action, because it was added to the patent by the certificate." *Id.* at 1297. Although the certificate of correction at issue in *Southwest Software* was issued under §254, and the certificate of correction at issue in the present case issued under §255 (because the error was Merck's fault), the provision limiting the effect of a certificate to causes of action thereafter arising is essentially identical in the two

provisions. *See ISCO II*, 2003 U.S. Dist. LEXIS 3262, at *9 n.1 ("To the extent that the statutes are analogous, the court believes *Superior Fireplace* [*v. Majestic Prods. Co.*, 270 F.3d 1358 (Fed. Cir. 2001)] is relevant and instructive. In addition, the distinction would tend to support the court's holding, in that it would be illogical for the standard for correcting a mistake of the PTO to be more strict than the standard for correcting an error of the patent applicant himself."); *accord*, *SDS USA, Inc. v. Ken Specialties, Inc.*, 2002 U.S. Dist. LEXIS 16762, at *72-*74 (D.N.J. Aug. 28, 2002).

In *ISCO I*, the plaintiff sought leave to amend its complaint under Fed. R. Civ., P. 15(a) after obtaining a certificate of correction under §254 to correct PTO error in the language of an asserted claim. 2002 U.S. Dist LEXIS 21706, at *6-*7. In *ISCO I*, this Court exercised its discretion to deny the plaintiff's motion, because the plaintiff's motion was "an attempt to circumvent the rule announced in *Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280 (Fed. Cir. 2000)." 2002 U.S. Dist. LEXIS 21706, at *5-*6. The Court concluded that a certificate of correction issued under §254 "is only effective for causes of action arising after it was issued." *Id* at *6.

The Court explained its decision as follows:

> Clearly, and despite the plaintiff's insistence to the contrary, the Certificate of correction which issued on February 19, 2002 is not effective in this case, which arose on July 17, 2001. Were the court to grant ISCO's request to relate an amended complaint back to the date of the issuance of the Certificate, thereby rendering the Certificate effective for purposes of this litigation, *Southwest* would be stripped of all meaning. The court will not accede to such a transparent and ill-informed invitation to ignore the Federal Circuit's clear mandate, as well as the language of 35 U.S.C. § 254. Because an amended complaint would relate back to the date of the original complaint, July 17, 2001, and because the Certificate of Correction issued after that date, granting leave to amend would be utterly futile as a matter of law.

Id. at *6-*7.

This reasoning governs Merck's motion to supplement its complaint in the present case, because it is nothing more or less than an attempt to end-run the mandate of *Southwest Software*, and avoid the clear language of §255.[5]

As the Court noted in *ISCO I*, its holding that the certificate of correction could not be made effective in the litigation by amendment of pleadings is supported by other district court decisions. ISCO I, 2002 U.S. Dist. LEXIS 21706, at *6, *citing Rambus, Inc. v. Infineon Techs. AG*, 155 F. Supp. 2d 668, 677 n.6 (E.D. Va. 2001) ("Federal Circuit law clearly holds that a patent holder cannot rely on a certificate of correction in a patent infringement suit filed before the certificate issues"); *Electronic Planroom v. McGraw-Hill Cos.*, 135 F. Supp. 2d 805, 827 (E.D. Mich. 2001) ("a certificate of correction has no effect on litigation pending at the time it is issued"); *Adrain v. Hypertech, Inc.*, 2001 U.S. Dist. LEXIS 19182, 2001 WL 740542, at *3 (D. Utah Apr. 18, 2001) ("It is clear that the certificates of correction, once issued, have prospective application.").

Merck evidently hopes to avoid the holding of *ISCO I* by filing a supplemental complaint rather than an amended complaint, but this maneuver is unavailing. In *Rohm Co., Ltd. v. Nichia Corp.*, 2003 U.S. Dist LEXIS 22227 (E.D. Pa. Nov. 26, 2003) Rohm filed a motion for leave to file a supplemental complaint, in an attempt to establish a new filing date for the action. *Id.* at *7. Rohm's original complaint was filed prior to the issuance of a certificate of correction, and Rohm sought to establish a new filing date, so that the Certificate might be effective in the pending action. *Id.* at *7.

Applying *Southwest Software*, the court concluded that the relevant certificate of correction, filed eleven months after the filing of the complaint, was "ineffective for the current action." *Id.* at *7. The basis of the court's ruling was that under *Southwest Software*, a certificate

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[5] Merck's attempt to distinguish this case from *ISCO I* (Merck's Brief, D.I. 49 at p. 9) confuses a cause of action for infringement with individual acts of infringement, as discussed below.

of correction is not effective as to a cause of action arising before the certificate was issued. *Id.* at *6-*7. With respect to Rohm's attempt to supplement its complaint to establish a new filing date for the action, the court stated that "[g]ranting Rohm the requested leave would permit an end run around the clear language of *Southwest*." *Id.* at *8. Despite the liberal pleadings allowed under Fed. R. Civ. P. 15(d), the court stated that "courts need not allow supplemental pleadings if the efforts would be futile" and explained that "[a]n amendment is considered futile 'if the amendment will not cure [any] deficiency in the original complaint or if the amended complaint cannot withstand a motion to dismiss.'" *Id.* at *8, *quoting Glaziers v. Glass Workers Union Local No. 252 Annuity Fund.*, 155 F.R.D. 97, 100 (E.D. Pa. 1994), in turn *quoting Jablonski v. Pan American World Airways, Inc.*, 863 F.2d 289, 292 (3d Cir. 1988). In the present action, as in *Rohm*, the proposed supplemental complaint would be futile because it would not avoid the mandate of *Southwest Software*.

In *Electronic Planroom v. McGraw-Hill Cos.* 135 F. Supp. 2d 805 (E.D. Mich. 2001), the plaintiff alleged infringement of a patent which issued with a facially defective claim to benefit of a prior patent application. *Id.* at 826. After filing the lawsuit, the patentee filed a petition for a certificate of correction, seeking to designate the patent-in-suit as a continuation-in-part of an earlier patent application, in order to avoid the patent issuing from that application as prior art. *Id.* Although the certificate of correction had not issued, the court rejected this maneuver, stating that "the Federal Circuit recently held that a certificate of correction has no effect on litigation pending at the time it is issued." *Id.*, *citing Southwest Software, Inc. v. Harlequin Inc.*, 226 F.3d 1280, 1293-97 (Fed. Cir. 2000). Consequently, the patent-in-suit was not a continuation-in-part of the earlier application "for purposes of this litigation." *Electronic Planroom*, 135 F. Supp. at 827.

In *Rambus, Inc. v. Infineon Techs. AG*, 155 F. Supp. 2d 668 (E.D. Va. 2001), the court found it "noteworthy that Rambus even sought to continue to press patent claims which contained typographical errors, even though Federal Circuit law clearly holds that a patent holder cannot rely

on a certificate of correction in a patent infringement suit filed before the certificate issues." *Id.* at 677 n.6, citing *Southwest Software*. Like Merck in the present action, "rather than concede the obvious, Rambus marched ahead with these claims until the Court ruled that it could not properly assert those claims. That meant, of course, that Infineon had to incur additional attorneys' fees to prove the utter lack of merit in Rambus' position." *Id.*

A number other district courts agree with *ISCO I* and the cases cited therein, and hold that a certificate of correction issued after the commencement of a lawsuit has no effect in the lawsuit.

In *STMicroelectronics, Inc. v. Motorola, Inc.*, 327 F. Supp. 2d 687 (E.D. Tex. 2004), the error in a claim of Motorola's asserted Davies patent was the recitation of a "first" region, which Motorola argued should be changed to "second," urging that this was a "typographical error." *Id.* at 699-700. The court first considered whether a certificate of correction was "timely enough to be considered in this lawsuit" under *Southwest Software*. *Id.* at 700. In *STMicroelectronics*, ST initially filed suit alleging infringement of its patent on July 18, 2003. The PTO issued a certificate of correction of Motorola's Davies patent on July 29, 2003. *Id.* at 701. In September, after the certificate issued, Motorola counterclaimed for infringement of the Davies patent. *Id.* Although the counterclaim was filed after the certificate issued, the court concluded that it could give no effect to the certificate of correction in the litigation under *Southwest Software*, because Motorola's cause of action arose before the certificate of correction issued. *Id.* at 701.

The court considered that under *Southwest Software*, the relevant inquiry is when the cause of action arose rather than when suit was filed. *Id.* at 700. Even though Motorola's counterclaim was filed after the certificate issued, the court concluded that Motorola's cause of action arose prior to issuance of the certificate, reasoning as follows:

> Although it is possible that Motorola's cause of action for infringement of the Davies patent arose in the one and a half months between the certificate's issuance and the relevant counterclaim, the Court makes a factual determination that the cause of action did not. First, the certificate of correction appears

> to have been obtained solely for this litigation because it was issued 11 years after the Davies patent was issued and sought only after ST had originally filed suit against Motorola. Such delay suggests that after ST filed suit: Motorola investigated ST products, then discovered potential infringement, then discovered the patent's error, and then requested a certificate of correction. Second, considering the complexity of the technology at issue, the Court finds it highly unlikely that in the one and a half months between the certificate's issuance: the accused infringer (ST) began infringing, Motorola discovered the infringement, and Motorola subsequently had time to draft and assert a counterclaim for infringement. Third, the parties have presented no evidence that Motorola's cause of action arose before [*sic*] the certificate of correction issued. On the evidence currently available, the Court makes a factual finding that Motorola's cause of action arose before the certificate of correction issued.

Id. at 701. In the absence of an effective certificate of correction, the court considered that it lacked authority to rewrite the claim, by substituting "second" for "first" in the claim. *Id.* at 703-04.

As discussed below, in the present case Ranbaxy's second and third ANDAs were filed in the summer of 2007, and Ranbaxy informed Merck of these filings on September 14, 2007 and provided copies of the relevant documents on October 17, 2007. It is accordingly clear that any "cause of action" asserted by Merck in its proposed supplemental complaint which relates to these filings also arose prior to issuance of the certificate of correction.

Under the court's reasoning in *STMicroelectronics*, a certificate of correction which issues after an infringement action is filed is given no consideration, because the cause of action for infringement arises prior to filing the action. It is apparent from the decision that the infringement of the Davies patent alleged in Motorola's counterclaim continued after issuance of the certificate of correction, and that the certificate of correction was not given prospective effect after it issued, but was held to be ineffective for any purpose in the litigation of Motorola's infringement counterclaim.

In *SDS USA, Inc. v. Ken Specialties, Inc.*, 2002 U.S. Dist. LEXIS 16762 (D.N.J. Aug. 28,

2002), SDS filed its action four months before requesting a certificate of correction from the PTO, which issued some eight months after the action was filed. *Id.* at *72. Defendant Ken argued that the certificate of correction was "irrelevant because the Federal Circuit in *Southwest Software* held that under the language of 35 U.S.C. §254, a certificate of correction does not have a retroactive effect" and urged that the patent was invalid for lack of written description without the certificate of correction. *Id.* at *71-*72. SDS urged that a certificate of correction because of an applicant's mistake under 35 U.S.C. §255 should be treated differently from a certificate of correction because of the PTO's mistake under 35 U.S.C. §254. *Id.* at *72. The Court rejected this argument, stating as follows:

> Moreover, the two statutes employ the identical language: that the effect of a patent with a certificate of correction would be "for causes thereafter arising as if the same had been originally issued in such corrected form." *Southwest Software*, 226 F.3d at 1296. Further, the *Southwest Software* Court discounted the holding of *Eagle Iron Works v. McLanahan Corp.*, 429 F.2d 1375 (3d Cir. 1970) in which the Third Circuit applied a Section 255 certificate of correction retroactively. *Southwest Software*, 226 F.3d at 1296-97. Consequently, if the '919 patent fails to disclose a best mode without the certificate of correction, the patent is invalid because a certificate issued after the initiation of a lawsuit cannot be given retroactive effect.

Id. at *73-*74 (footnote omitted).

In *SDS*, the patentee amended its complaint to allege infringement of the '919 patent in February 1999 (*id.* at *83-*84), and the certificate of correction issued in November 1999. *Id.* at *72. It is clear that the alleged infringement continued after the certificate of correction issued, because in May 2000, SDS filed a motion for leave to file an amended complaint adding the president of Ken as a defendant on the basis that he "has induced and continues to induce infringement of the '919 patent." *Id.* at *5. By the time of the court's August 2002 decision, finding a genuine issue of material fact with respect to inducement (*Id.* at *23-*24), SDS alleged that Ken had sold over 300 infringing machines and had completely replaced its prior machine

with the MultiBender machine accused of infringement. *Id.* at *67-*68. The certificate of correction thus was not given prospective effect after it issued, but was held to be ineffective for any purpose in the litigation.

The court in *Mobile Hi-Tech Wheels v. CIA Wheel Group*, 2007 U.S. Dist. LEXIS 68760 (C.D. Cal. Mar. 20, 2007) held that "[p]laintiff filed this lawsuit prior to filing either of the certificates of correction. As a result, neither of the correction requests are to be given effect. Instead, the Court must consider the [asserted] patent as it existed at the filing of the lawsuit." *Id.* at *13-*14, *citing Southwest Software,* 226 F.3d at 1294 ("A certificate of correction is only effective for causes of action arising after it was issued").

In *Karol v. Burton Corp.*, 234 F. Supp. 2d 450 (D. Vt. 2002), following issuance of the patent in suit, Karol filed a certificate of correction with the PTO. *Id* at 452. The PTO did not issue the certificate of correction until after Karol filed the lawsuit. The Court ruled that "[a]ccordingly, the patent before the Court in the present dispute is the uncorrected version of the [asserted] patent." *Ibid*, citing *Southwest Software,* 226 F.3d at 1294 ("Certificate of correction is only effective for causes of action arising after it was issued").

In *Nova Measuring Instruments, Ltd. v. Nanometrics Inc.*, 2006 U.S. Dist. LEXIS 90736 (N.D. Cal. Dec. 1, 2006), the court ruled that a certificate of correction was inapplicable in the lawsuit, "because plaintiff filed the instant action before the PTO issued the certificate." *Id.* at *10 n.11, *citing Southwest Software,* 226 F.3d at 1294-95 ("holding certificate of correction 'not effective' with respect to cause of action arising before issuance of certificate").

Merck is unable to cite a single decision holding that a certificate of correction is effective from the date of its issuance, although the certificate issues after commencement of litigation, apart from *Central Admixture Pharm. Servs., Inc. v. Advanced Cardiac Solutions, P.C*, 2006 U.S. Dist. LEXIS 95833 (N.D. Ala. Jan. 10, 2006), *reversed in pertinent part*, 482 F. 3d 1347 (Fed. Cir. 2007). That case has no precedential value, because the district court's

finding that the certificate of correction was valid was reversed (not vacated, as Merck states). 482 F.3d 1347, 1357 (Fed. Cir. 2007).

Although Merck also relies on *Alltrade Tools, LLC v. Olympia Group, Inc.*, 2003 U.S. Dist. LEXIS 26248 (C.D. Cal. Oct. 10, 2003), the decision expressly states that "The Court need not consider the effect of Olympia's Certificate of Amendment [*sic*] But it would appear that the error—the failure to included [*sic*] the earlier date in the patent-was on the part of PTO, since the Preliminary Amendment properly included the reference to the prior application." *Id.* at *10 n.1. The statement that "[h]ad the Motion been granted, 35 U.S.C. §255 would still allow for prospective relief after a Certificate of Correction has been issued that would provide Olympia the benefit of the earlier filing date" is simply dictum, in a decision which fails even to cite *Southwest Software*. *Id.* at *11.

Merck also cites *National Prods., Inc. v. Palmetto West Trading Co., LLC*, 2006 U.S. Dist. LEXIS 28682 (W.D. Wash. May 4, 2006) as "suggesting parties could request to amend their infringement and invalidity allegations based on a recently issued COC." This "suggestion" is not otherwise explained, and appears to relate to the assumption that the certificate of correction could alter the court's claim construction "for any cause of action arising post-Correction." *Id.* at *2-*3. The "suggestion" is thus obscure at best, and is far from a reasoned analysis of the issue now before this Court.

The reversed decision in *Central Admixture* and the equivocal statements in *Alltrade* and *Palmetto* are against the great weight of reasoned precedent considered above, which Merck fails to acknowledge or consider.

Merck also incorrectly maintains that in *Southwest Software* "[t]he court expressly stated that the COC at issue in *Southwest Software* would be effective if any additional infringement occurred in the future." (Merck's Brief, D.I. 49 at p. 10). As discussed below, Merck fails to appreciate that a single cause of action for infringement includes a series of separate acts,

including continuing sales of a single product accused of infringing a single patent. According to the Federal Circuit, a certificate of correction is treated as a part of the original patent only if the "cause of action" arises after correction, which is a different question from whether infringement continues after issuance of the certificate of correction. *Southwest Software* does not suggest that a patentee may split a single cause of action, for infringement of the same patent claims by the same infringing product, in order to obtain prospective effect of a certificate of correction which issued after the single cause of action for patent infringement arose.

Contrary to Merck's assumption, the issue of the effectiveness of a certificate of correction does not depend on whether infringement continues after the issuance of a certificate of correction, but rather whether the cause of action stated in the complaint or counterclaim arises before issuance of the certificate. A cause of action for infringement arises before the filing of the complaint in an action alleging infringement under 35 U.S.C. §271(a), (b), or (c), or in an action under 35 U.S.C. §271(e)(2). This fact supports the reasoning of courts which have equated the filing of a lawsuit with the "cause of action" specified in 35 U.S.C. §255.

C. Merck's Cause of Action Arose Prior to the Certificate of Correction

Merck has a single cause of action, based on allegations of infringement of the '868 patent by a single product—the combination of imipenem and cilastatin which has been approved by the FDA, which Ranbaxy will import and sell in the United States following approval of its ANDAs. The ANDAs relate to different packaging containing the same active pharmaceutical ingredients. However it may be packaged, there is only one allegedly infringing pharmaceutical composition that will be imported or sold by Ranbaxy, which was fully described in Ranbaxy's ANDA filed prior to commencement of the present litigation.

1. Merck's Original Complaint

In its original complaint, filed prior to issuance of the certificate of correction, Merck separately alleged infringement of the uncorrected '868 patent under 35 U.S.C. §271(a), (b) or

(c) (Count I) as well as infringement under §271(e)(2) (Count II).

In Count I, which relates to future commercial infringement, Merck alleged that Ranbaxy had made meaningful preparations for, and engaged in activities directed toward, infringing the '868 patent. (Complaint, D.I. 1, ¶ 14). Merck further alleged that "Defendants' manufacture, use or offer for sale of the *ANDA products* in the United States of importation of the *ANDA products* into the United States will constitute patent infringement under 35 U.S.C. § 271(a), (b), or (c)." (Complaint, D.I. 1, ¶ 16) (emphases added). Merck further alleged that "An actual controversy now exists between Merck and Defendants with respect to the infringement of the '868 patent." (Complaint, D.I. 1, ¶ 17). Merck sought relief including an order enjoining Ranbaxy from "manufacturing, using, selling and offering for sale the *ANDA products*." (Complaint, D.I. 1, Prayer for Relief, subsection c) (emphasis added).

In Count I, Merck pled its cause of action for infringement as follows: "On information and belief, Defendants were aware of the existence of the '868 patent and were aware that the marketing, manufacture, use, offer for sale and sale of the *ANDA products* would constitute an act of infringement of the '868 patent." (Complaint, D.I. 1, ¶ 21) (emphasis added).

The cause of action for patent infringement pled by Merck in Count I of the original complaint is thus an action for infringement of the '868 patent under 35 U.S.C. §271(a), (b) or (c) based on Ranbaxy's future importation and commercial sale of its "ANDA products." This cause of action for infringement by importation and sale of the ANDA products arose at latest by the time Merck filed its original complaint pleading this cause of action. With respect to the trial of any action relating to Merck's original allegations of infringement under §271(a), (b), or (c), including any future importation and sale of Ranbaxy's "ANDA products," the certificate of correction issued after Merck filed its original complaint and after Merck's cause of action based on future sales of the ANDA products arose.

Whatever the additional allegations in Merck's new complaint may be, they cannot avoid

the consequence that any trial relating to infringement under §271(a), (b) or (c), including the invalidity defenses pled in Ranbaxy's original Answer and Counterclaims, will involve the original '868 patent without additional matter introduced in the certificate of correction. Because Merck generally alleged infringement based on the future importation and sale of Ranbaxy's "ANDA products," the trial of any issue of infringement relating to any of Ranbaxy's generic products, including the invalidity defenses pled by Ranbaxy, will be based on the original '868 patent, excluding the additional reference inserted by the certificate of correction.

With respect to Merck's original allegations of infringement under 35 U.S.C. §271(e)(2), based on the filing of Ranbaxy's ANDA (Count II), Merck's cause of action also arose prior to commencement of the present litigation, and trial of these issues and defenses must also proceed on the basis of the original '868 patent. The "artificial" act of infringement under §271(e)(2) is also based on likely future infringement under §271(a), (b), or (c) by the actual product that will be commercially marketed following approval of an ANDA. *See Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1355-56 (Fed. Cir. 2003) (§271(e)(2) does not make the filing of an ANDA an act of infringement unless the ANDA seeks approval to make, use or sell the drug that would otherwise infringe the patent apart from §271(e)(2), and a patentee must prove that the generic manufacturer's manufacture, use or sale would nonetheless infringe the patent under a traditional infringement analysis). To the extent that Merck has a cause of action under §271(e)(2) in the present case, it is the same cause of action as its allegations of infringement under §271(a), (b) and (c), because it is based on the same future acts of alleged commercial infringement.

2. Merck's Proposed Supplemental Complaint

Merck now seeks leave to supplement its complaint with allegations relating to infringement of "ANDA products" described in two ANDAs filed by Ranbaxy in the summer of 2007, well prior to issuance of the certificate of correction. (Supp. Complaint, D.I. 48a, ¶¶ 49,

63). These ANDAs relate to the same allegedly infringing combination of imipenem and cilastatin, in different packaging. Ranbaxy informed Merck of these ANDAs on September 14, 2007, and provided copies of the ANDAs to Merck on October 17, 2007, before issuance of the certificate of correction. (Proposed Supplemental Complaint, D.I. 48a, ¶¶ 50, 64). Merck alleges future infringement by these "ANDA products" under §271(a), (b) or (c). (Proposed Supplemental Complaint, D.I. 48a, ¶¶ 54, 55, 68, 69). With respect to the two ANDAs filed in the summer of 2007, Merck admits that the ANDA products described in these additional ANDAs "contain imipenem and cilastatin in the same dosages as Product I for the same use as injections." (Merck's Brief, D.I. 49 at p.2). Merck further states that in the present action, "Discovery has been proceeding on all three ANDAs and Products I, II, and III." (Merck's Brief, D.I. 49 at p. 2). Merck represents that "the issues relating to infringement should be the same for Products I, II and III." (Merck's Brief, D.I. 49 at pp. 2-3).

D. Ranbaxy's Cause of Action Arose Prior to the Certificate of Correction

In its original Answer and Counterclaims, Ranbaxy admitted that "by letter of January 22, 2007, it notified Merck of its ANDA filing; that its proposed *injectable products* would not infringe any valid claim of the '868 patent, and that Ranbaxy planned to begin marketing its proposed injectable product immediately upon approval." (Answer, D.I. 10, ¶ 11) (emphasis added). Ranbaxy further admitted that "it has complied with the applicable regulatory requirements in filing its ANDA, and that it has developed and carried out testing on the proposed *injectable products* that it has developed." (Answer, D.I. 10, ¶ 12) (emphasis added). Ranbaxy also admitted that it "manufactures a composition containing imipenem and cilastatin sodium in India and markets and sells that composition in India and Peru" and "that it is prepared to import its proposed *injectable products* into the United States and that it has the capacity to manufacture and market its proposed *injectable products* immediately upon approval of its ANDA." Ranbaxy pled as a defense the invalidity of the '868 patent. (Answer, D.I. 10, ¶¶ 37

and 38) (emphases added).

Ranbaxy also counterclaimed for a declaratory judgment that the '868 patent is invalid, unenforceable, and/or not infringed by the proposed *injectable products* comprising imipenem and cilastatin sodium in Ranbaxy's ANDA. (Answer, D.I. 10, Demand for Judgment, subsection 3) (emphasis added). Ranbaxy described its cause of action as "an action based on an actual controversy between Ranbaxy and Merck concerning the invalidity and/or noninfringement of the '868 patent-in-suit, and Ranbaxy's right to continue to seek approval of its ANDA for its proposed *injectable products*, and upon approval by the FDA, to manufacture use, sell and offer to sell and import into the United States its proposed *injectable products*." (Answer, D.I. 10, ¶ 46) (emphases added). In Counterclaim I, Ranbaxy seeks a declaratory judgment that its "proposed *injectable products* do not infringe any valid claim of the '868 patent, either literally or under the doctrine of equivalents." (Answer, D.I. 10, ¶ 56) (emphasis added). Ranbaxy's cause of action also includes Counterclaim II, seeking a declaratory judgment that "Each and every claim of the '868 patent is invalid for failure to meet the statutory requirements of Title 35 of the United States Code, including, but not limited to, the failure to comply with one or more of the requirements of 35 U.S.C. §§101, 102, 103, and/or 112."

Ranbaxy's counterclaim cause of action arose prior to issuance of the certificate of correction, and trial on the validity issues raised by this cause of action must also exclude the certificate of correction.

E. Merck Cannot Split Its Single Cause of Action for Infringement

Merck's theory concerning its cause of action for infringement of the '868 patent, with respect to the counts added to its proposed supplemental complaint, is as follows: "If Ranbaxy ever attempts to launch its products, Ranbaxy's sales activity will necessarily occur after the COC was issued and will therefore be an infringement of the patent *with the COC*. Thus, a central issue in the parties' dispute is whether the patent *with the COC* would be infringed by

future sales." (Merck's Brief, D.I. 49 at p. 6). The crux of Merck's argument is that "if these counts are not added to the case, Merck could file an additional lawsuit in the future to adjudicate whether Ranbaxy's products infringe the patent with the COC, in particular with respect to the new causes of action that would arise when Ranbaxy launched any cilastatin-containing products." (Merck's Brief, D.I. 49 at p. 6).

According to this argument, each separate future sale of Ranbaxy's ANDA products constitutes a separate "cause of action" under 35 U.S.C. §271(a), (b), or (c). (Merck's Brief D.I. 49 at p. 7). Merck misunderstands the meaning of "cause of action" in arguing that "[t]here can be no dispute that if Ranbaxy actually launches a cilastatin-containing product, that activity in the future will create multiple new causes of action arising well after the issuance of the COC." (Merck's Brief, D.I. 49 at p. 7). On the contrary, there can be no dispute that Merck has already pled any cause of action that it may have for future infringement of the '868 patent by future importation and sale of Ranbaxy's ANDA products, in Counts I and II of Merck's initial declaratory judgment complaint. It is also beyond dispute that this single cause of action arose before issuance of the certificate of correction.

Merck's argument that each separate act of future infringement constitutes a separate "cause of action" is meritless because the law is clear that a party may not split a single cause of action, for infringement of a single patent by a single product sold by a single defendant, into a limitless number of "multiple" causes of action, theoretically resulting in thousands or millions of separate lawsuits each based on a single future commercial sale of Ranbaxy's commercial products.

1. Merck Has a Single Cause of Action for Future Infringement

The law of the Federal Circuit is clear, and is stated in *Mars, Inc. v. Kabushiki-Kaisha Nippon Conlux*, 58 F.3d 616, 619-20 (Fed. Cir. 1995) as follows:

> It is well established that a party may not split a cause of action into separate grounds of recovery and raise the separate grounds in successive lawsuits; instead, a party must raise in a single lawsuit all the grounds of recovery arising from a single transaction or series of transactions that can be brought together. See *Restatement (Second) of Judgments* § 24(2) (1982) (all actions arising from the same transaction or series of transactions are regarded as constituting a single cause of action); *Gregory v. Chehi*, 843 F.2d 111, 117 (3d Cir. 1988) (for purposes of claim preclusion analysis, the term "claim" is defined "broadly in transactional terms, regardless of the number of substantive theories advanced in the multiple suits by the plaintiff") (citing *Restatement (Second) of Judgments*); *Foster v. Hallco Mfg. Co.*, 947 F.2d at 478-79, 20 U.S.P.Q.2D (BNA) at 1248-49 (same); *Alyeska Pipeline Service Co. v. United States*, 231 Ct. Cl. 540, 688 F.2d 765, 769-70 (Ct. Cl. 1982) (same; "claim splitting cannot be justified on the ground that the two actions are based on different legal theories"), *cert. denied*, 461 U.S. 943, 77 L. Ed. 2d 1301, 103 S. Ct. 2120 (1983).

In that case, Mars initially sued Conlux USA, alleging that it had infringed a patent under §271(b), by inducing others to use a coin changer produced by Nippon Conlux in Japan, and the initial trial resulted in a verdict favorable to Mars. *Mars*, 58 F.3d at 617. Nippon Conlux was not joined as a defendant in the first action, and Mars filed a separate infringement action under §271(b), alleging that Nippon Conlux had induced Conlux USA and others to infringe the patent, and also alleging infringement under §271(g), based on Nippon Conlux's importation of the coin changers into the United States. *Id.* at 617-18. The district court granted Nippon Conlux's motion for summary judgment on claim preclusion grounds in the second suit. *Id.* at 618. The Federal Circuit affirmed this decision, explaining as follows:

> Ultimately, Mars stakes its case on the proposition that a plaintiff may sue each distinct tortfeasor separately, and that the liability of each gives rise to a separate cause of action that can support a separate suit for damages. While that may be true as to unrelated parties, a plaintiff who chooses to bring two separate actions against two tortfeasors who are jointly responsible for the same injury runs the risk that the court will find the parties sufficiently related that the second action is barred by claim preclusion.

Id. at 620. In *Mars, Inc. v. Kabushiki-Kaisha Nippon Conlux*, the Federal Circuit stated that the

issue of claim preclusion was governed by Third Circuit law. 58 F.3d at 618.

The rule against claim splitting would bar any future infringement action against Ranbaxy, because Merck's present cause of action "consists of all rights against a particular defendant 'with respect to all or any part of the transaction, or a series of connection transactions, out of which the action arose.'" *Alyeska Pipeline Serv. Co. v. United States*, 688 F.2d 765, 769 (Ct. Cl. 1982), quoting *Container Transport Int'l, Inc. v. United States*, 468 F.2d 926, 929 (Ct. Cl. 1972). Regardless of whether Merck alleges infringement under §271(a), (b) or (c), or §271(e)(2), its cause of action is one and the same, since "claim splitting cannot be justified on the basis that the two actions are based on different legal theories." *Alyeska*, 688 F.2d at 769.

In an action involving a declaratory judgment claim of non-infringement, the Federal Circuit held that a subsequent infringement action brought by the declaratory judgment defendant was barred because the infringement counterclaim was compulsory in the original declaratory judgment action. *Polymer Indus. Prods. Co. v. Bridgestone/Firestone, Inc.*, 347 F.3d 935, 937 (Fed. Cir. 2003) ("this court reiterates that a claim for a declaration of noninfringement makes a counterclaim for patent infringement compulsory. Although not explicit in the text of Rule 13(a), a party that does not assert its compulsory counterclaim in the first proceeding has waived its right to bring the counterclaim and is forever barred from asserting that claim in future litigation."). Even if Merck had not alleged future infringement as its cause of action under §271(a), (b), or (c) in its initial complaint, any counterclaim relating to this cause of action would have been compulsory in Ranbaxy's counterclaim declaratory judgment action.

Whether the issues of future infringement by actual commercial sale of Ranbaxy's ANDA products and the validity of the '868 patent are resolved in Merck's original action, or in Ranbaxy's counterclaim action, any damages based on future commercial importation and sale of the ANDA products would necessarily be awarded in the present lawsuit under 28 U.S.C. §2202, as "further relief" based on a declaratory judgment of infringement and validity in the present

action. *Polymer Indus. Prods. v. Bridgestone/Firestone*, 347 F.3d at 939. Any subsequent infringement action(s) filed by Merck seeking damages based on such sales would be "forever barred."

Merck fails to appreciate that although patent infringement often consists of a series of sales of the same product, this conduct does not give rise to a series of separate causes of action for infringement, that can be endlessly litigated in subsequent actions. This distinction is explained by the Federal Circuit in *Young Eng'rs, Inc. v. International Trade Comm'n*, 721 F.2d 1305 (Fed. Cir. 1983). In that case, the patent owner filed an initial action for infringement by two products imported by the defendant, which was dismissed with prejudice in 1972. *Id.* at 1307-08. In 1982, the patent owner initiated a proceeding in the ITC alleging infringement of the same patent, based on continuing importation and sale of the products. *Id.* at 1308. With respect to the "cause of action" asserted by the patent owner, the ITC considered that its unfair trade practice investigation under 19 U.S.C. §1331(a) was not the same "cause of action" as the earlier patent suit, stating that "the acts complained of here all happened *subsequent* to dismissal of the court case, and are apparently occurring on a larger scale" and because the importer had introduced 8 new models of imported products within the last 18 months. *Id.* at 1313.

The Federal Circuit rejected this theory, considering that the question of whether a series of acts of infringement constitute a unitary "claim" or "cause of action" for infringement should be determined pragmatically. *Id.* at 1315 (following *Restatement (Second) of Judgments* (1982) §24). Following this approach "[i]f a patent owner has unsuccessfully attacked an alleged infringer for the same infringing acts in a prior court proceeding, no substantive argument has been advanced as to why the patent owner should be given an opportunity to put forth the same charge of infringement again" in an administrative proceeding. *Ibid.* The controlling issue in defining the scope of a "cause of action" for infringement is not whether sales of a product accused of infringement continue after a judgment in a first action, but whether the product

accused of infringement in the subsequent action is the same product that was at issue in the prior litigation. *Id.* at 1316. As the court explained:

> With respect to patent litigation, we are unpersuaded that an "infringement claim," for purposes of claim preclusion, embraces more than the specific devices before the court in the first suit. Adjudication of infringement is a determination that a thing is made, used or sold without authority under the claim(s) of a valid enforceable patent. Thus, the status of an infringer is derived from the status imposed on the thing that is embraced by the asserted patent claims, the thing adjudged to be infringing. By the same token, where the alleged infringer prevails, the accused devices have the status of noninfringements, and the defendant acquires the status of a noninfringer to that extent.

Ibid., citing *Molinaro v. AT&T Co.*, 460 F. Supp. 673 (E.D. Pa. 1978), *aff'd without opinion*, 620 F.2d 288 (3d Cir. 1980) (footnote omitted);[6] *see also*, *Abbott Labs. v. Bayer Healthcare LLC*, 2005 U.S. Dist. LEXIS 18361 (D. Del. Aug. 29, 2005) (following *Young Engineers*).

In *Young Engineers*, the ITC investigation was not precluded by the earlier district court action, only because the respondent did not carry its burden to establish the defense by showing that the devices at issue were the same as those in the earlier infringement suit. 721 F.2d at 1317. In the present case, the combination of imipenem and cilastatin alleged to infringe in Merck's original complaint is the same product now accused of infringement in Merck's proposed supplemental counts, as Merck admits. (Merck's Brief, D.I. 49 at pp. 2-3). Merck has only a single cause of action for infringement of any ANDA product containing the same accused compound, regardless of its packaging. *See Roche Palo Alto LLC v. Apotex, Inc.*, 2007 U.S. Dist. LEXIS 67058, at *29-*31 (N.D. Cal. Sept. 11, 2007) (same infringement claim was raised in second suit where differences in concentration of the formulation of a second ANDA, which

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[6] The *Molinaro* decision involved an infringement action against AT&T, that was held to be precluded by the dismissal with prejudice of a separate infringement action against AT&T's supplier (Motorola) for failure to comply with discovery orders. 460 F. Supp. at 674-75, citing *Kessler v. Eldred*, 206 U.S. 285, 289 (1907).

contained identical ingredients, were unrelated to the limitations in the claim of the patent, and therefore could not prevent the application of claim preclusion).

In the context of the equitable laches defense to patent infringement, the Federal Circuit further explained that although patent infringement is a "continuing tort," such "continuing tortious acts may be deemed to constitute a unitary claim." *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1031 (Fed. Cir. 1992) (*en banc*) (citing *Young Engineers,* 721 F.2d at 1316, for the principle that "claim preclusion applies against same type of infringing acts"). This analysis is consistent with the *Restatement*, which considers successive act or events as a single "transaction" or "connected series" when a defendant is accused of "acts which though occurring over a period of time were substantially of the same sort and similarly motivated" and concludes that "fairness to the defendant as well as the public convenience may require that they be dealt with in the same action." *Restatement (Second) of Judgments* § 24(2) (1982), comment *d*. Applying the "pragmatic standard" of the Restatement, the "series of connected transactions" involved in the sale of identical products accused of infringing the same patent claim is a single claim or cause of action, regardless of whether sales are continuing, because "transaction" connotes "a natural grouping or common nucleus of operative facts." *Id.*, comment *b*.

2. Merck's Reliance on *Hazelquist* is Misplaced

Merck's reliance on *Hazelquist v. Guchie Moochie Tackle Co.*, 437 F.3d 1178 (Fed. Cir. 2006), is thus misplaced. (Merck's Brief, D.I. 49 at pp. 7-8). Nothing in *Hazelquist* suggests that a patent owner may bring successive actions alleging infringement of the same patent, by the same product, against the same defendant, on the basis that "each act of patent infringement gives rise to a separate cause of action." (Merck's Brief, D.I. 49 at p. 7). Merck's argument ignores the specific factual context of *Hazelquist*. That case did not involve an attempt to allege separate causes of action for infringement based on continuing sales of the same accused product. In *Hazelquist*, the patent owner filed an action for patent infringement that was stayed

during the pendency of a bankruptcy action by the defendant under 11 U.S.C. §362(a)(1). 437 F.3d at 1180. The district court dismissed the action after the defendant obtained a discharge of his debts in the bankruptcy proceeding. *Id.* at 1179-80. The Federal Circuit reversed the dismissal and reinstated the action. Because the defendant in the patent infringement action continued to infringe the patent after the date of bankruptcy discharge, the patent owner was entitled to damages for acts of infringement following the bankruptcy discharge, in the same lawsuit. *Id.* at 1181. Although the court in *Hazelquist* cites *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1031 (Fed. Cir. 1992), in *Aukerman* the *en banc* Federal Circuit instructed that a continuing series of infringing acts is a "unitary claim" that clearly does not permit the patentee to file multiple actions based on each separate act. *Hazelquist* is limited to its peculiar facts, and says nothing about a patent owner's ability to split a unitary cause of action based on continuing sales of a single allegedly infringing product.

F. Supplementing the Complaint Would Be Futile

In *ISCO I*, this Court exercised its discretion under Fed. R. Civ. P. 15(a) to deny the plaintiff's motion to amend its complaint, because the plaintiff's motion was "an attempt to circumvent the rule announced in *Southwest Software, Inc. v. Harlequin Inc*, 226 F.3d (Fed. Cir. 2000)." 2002 U.S. Dist. LEXIS 21706 at *5-*6. The Court ruled that a certificate of correction issued under §254 "is only effective for causes of action arising after it was issued." *Id.* at *6. The Court denied the motion to amend the complaint on the basis that "granting leave to amend would be utterly futile as a matter of law." *Id.* at *6-*7. As this Court held in *Medeva Pharma Ltd. v. American Home Prods. Corp.*, 201 F.R.D. 103, 104 n.1. (D. Del. 2001), "[t]he standard applicable to motions to amend under Fed. R. Civ. P. 15(d) is essentially the same standard that applies to Fed. R. Civ. P. 15(a)."

In *Rohm Co., Ltd. v. Nichia Corp.*, 2003 U.S. Dist LEXIS 22227 (E.D. Pa. Nov. 26, 2003), Rohm filed a motion for leave to file a supplemental complaint, in an attempt to establish

a new filing date for the action. *Id.* at *7. Rohm's original complaint was filed prior to the issuance of a certificate of correction, and Rohm sought to establish a new filing date, so that the Certificate might be effective in the pending action. *Id.* at *7. Despite the liberal pleadings allowed under Fed. R. Civ. P. 15(d), the court stated that "courts need not allow supplemental pleadings if the efforts would be futile" and explained that "An amendment is considered futile 'if the amendment will not cure [any] deficiency in the original complaint or if the amended complaint cannot withstand a motion to dismiss.'" *Id.* at *8, *quoting Glaziers v. Glass Workers Union Local No. 252 Annuity Fund v. Janney Montgomery Scott, Inc.*, 155 F.R.D. 97, 100 (E.D. Pa. 1994), in turn *quoting Jablonski v. Pan American World Airways, Inc.*, 863 F.2d 289, 292 (3d Cir. 1988).

In the present action, as in *ISCO I* and *Rohm*, Merck's proposed supplemental complaint would be futile because it would not avoid the mandate of *Southwest Software*. More specifically:

- Count III alleging infringement of the '868 patent with the certificate of correction would be futile, because ¶40 alleging future infringement under 35 U.S.C. § 271(a), (b) or (c) was also pled in the original complaint (Complaint D.I. 1, Count I, ¶16);
- Count IV alleging future infringement of the '868 patent with the certificate of correction by Ranbaxy's ANDA "Product II" under §271 (a), (b) or (c) (Supp. Complaint, D.I. 48a, ¶54) would be futile, because Ranbaxy's "Product II" is one of the same "ANDA products" accused of infringement in Merck's original complaint. (Complaint D.I. 1, Count I, ¶14.). The ANDA relating to this product was filed in the summer of 2007, and Ranbaxy both informed Merck of the second ANDA on September 14, 2007, and produced copies of the second ANDA to Merck on October 17, 2007, as Merck alleges. (Supp. Complaint, D.I. 48a, ¶¶49-50). Any cause of action that Merck may have with

respect to this ANDA product is the same cause of action originally pled, and also arose prior to issuance of the certificate of correction.

- Count V alleging future infringement of the '868 patent with the certificate of correction by Ranbaxy's ANDA "Product III" under §271 (a), (b) or (c) (Supp. Complaint, D.I. 48a, ¶68) would be futile, because Ranbaxy's "Product III" is one of the same "ANDA products" accused of infringement in Merck's original complaint. (Complaint D.I. 1, Count I, ¶14.). The ANDA relating to this product was filed in the summer of 2007, and Ranbaxy both informed Merck of the third ANDA on September 14, 2007, and produced copies of the third ANDA to Merck on October 17, 2007, as Merck alleges. (Supp. Complaint, D.I. 48a, ¶64). Any cause of action that Merck may have with respect to this ANDA product is the same cause of action originally pled, and also arose prior to issuance of the certificate of correction.
- Count VI would be futile, because the certificate of correction can have no effect in the trial of Ranbaxy's invalidity counterclaims, which arose prior to issuance of the certificate of correction. Furthermore, because the certificate of correction has no effect in the present litigation, the question of whether the '868 patent would be valid with the certificate of correction does not affect any issue in the present litigation. Merck thus seeks an advisory opinion with respect to the validity of the '868 patent including the certificate of correction, which can only arise in some other litigation.[7]

Furthermore, with respect to ANDA "Product II" and "Product III," these products are clearly the same as the original ANDA product, because the different packaging of these products is not claimed in the '868 patent. As Merck admits: "Products II and III have the same two active

[7] Merck's citation to *Adenta GmbH v. OrthArm, Inc.*, 501 F.3d 1364 (Fed. Cir. 2007) is inapposite. Both parties agree that there is jurisdiction under the Declaratory Judgment Act with respect to the issues of infringement and invalidity raised in the original pleadings.

ingredients as the first product at issue, including the cilastatin compound claimed in the '868 patent. Thus, the issues relating to infringement should be the same for Products I, II and III." (Merck's Brief, D.I. 49 at pp. 2-3). Merck has only a single cause of action for infringement of any ANDA product containing the same claimed compound, regardless of its packaging. *See Roche Palo Alto LLC v. Apotex, Inc.*, 2007 U.S. Dist. LEXIS 67058, at *29-*31 (N.D. Cal. Sept. 11, 2007).

V. CONCLUSION

Because Merck seeks to supplement its complaint with counts relating to a certificate of correction which issued after Merck's cause of action arose, its motion is utterly futile as a matter of law, and should be denied by the Court.

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Dated: January 31, 2008

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on January 31, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF and caused the same to be served on the defendant at the addresses and in the manner indicated below:

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